MAR 23 2001

K000977

Section II Summary and Certification

Summary of Safety and Effectiveness Information Pertaining To Substantial Equivalence

Device Common Name: Heat Exchanger Coils
Classification Name: Heat Exchanger, Cardiopulmonary Bypass

Intended Use:
The two heat exchanger coils submitted in this 510(k) are intended to regulate the temperature of the cardioplegia fluid and/or blood when the coils are submerged into a reservoir. The devices are intended to be used in procedures lasting up to 6 hours duration.

Descriptions:
The heat exchanger coils submitted in this 510(k) are used in adjusting the temperature of cardioplegia fluid and/or blood during bypass procedures. The coils provide a pathway for blood and cardioplegia solutions to be administered to the heart. These coils are for single use only and are not to be re-sterilized by the user.

The heat exchangers are generic in their structure in that they are each coiled structures with a straight section at either end for interfacing with tubing.

The materials used in the manufacturing of these coils include type-304 stainless steel (0006-00011) and polyvinylchloride tubing (0006-00012). Note: The cleared Gish heat exchanger coil is made from type-304 stainless steel.

Substantial Equivalence:
The two heat exchanger coils submitted in this 510(k) are substantially equivalent in intended use, design, technology/principle of operation, and performance to the cleared Gish Biomedical heat exchanger coil (K871774).

Principle of Operation/Technology:
The heat exchangers submitted in this 510(k) and the Gish heat exchanger all operate on the principles of heat transfer. The coils are submerged into water which transfers heat across the walls of the coil, thereby increasing or decreasing the temperature of the fluid inside the coil.

Design/Materials:
Differences in the materials between the heat exchangers indicated in this 510(k) and the Gish heat exchanger raise no new issues of safety and effectiveness.

Performance:
The performance of the heat exchangers presented in this 510(k) is substantially equivalent to the performance of the Gish heat exchanger.

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Additional Safety Information

Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10 to the negative sixth.

Ethylene oxide residuals will not exceed the maximum residue limits imposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

Blood contacting materials (polyvinylchloride) were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) contact duration]. The polyvinyl chloride materials were found to be biocompatible.

Note: Biocompatibility testing on the Stainless Steel coil was not performed as it is the exact same formula - type 304 Stainless Steel – that is used in the predicate Gish stainless steel coil. Therefore, its biocompatibility is confirmed.

The expiration dating of the submitted components is controlled by the component with the shortest expiry that is included in a kit, or two years; whichever is the shortest duration.

Conclusion

The convenience kit components submitted in this 510(k) are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared devices indicated within. Differences between the submitted components and the corresponding cleared device do not raise any new issues of safety or effectiveness.

Olson Medical Sales' statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended to be the basis for a patent infringement action.

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Summary of Safety And Effectiveness Information Pertaining To Substantial Equivalence

This Summary of Safety and Effectiveness was prepared on March 22, 2000.

This Summary was prepared by: Garry A. Courtney
Regulatory Affairs Specialist

This Summary was prepared for: OLSON MEDICAL SALES
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Ashland, MA 01721
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2001

Olson Medical Sales, Inc.
c/o Mr. Gary A. Courtney
Terumo Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
Elkton, MD 21921

Re: K000977
Trade/Device Name: OMS Heat Exchanger Coils (Stainless Steel Coil and Polyvinylchloride Coil)
Regulation Number: 21 CFR 270.4240
Regulatory Class: II
Product Code: DTR
Dated: January 2, 2001
Received: January 5, 2001

Dear Mr. Courtney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000977

Device Name: Components For Cardiovascular Procedure Kit – Heat Exchanger Coils

Indications For Use:

The **Heat Exchanger Coils** are intended to regulate the temperature of cardioplegia fluid and/or blood when the coils are submerged into a reservoir. The devices are intended to be used in procedures lasting up to 6 hours duration.

Garry A. Courtney
Regulatory Affairs Associate
Terumo Medical Corporation

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

3/22/1

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000977

(Optional Format 1-2-96)